

REMARKS

Claims 1-26 are pending and under examination.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1-26 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. Applicants submit that the claims are clear and definite. With regard to whether the claims refer to HIV-1, HIV-2 or both, the specification teaches that a suitable HIV immunogen can be a whole-killed HIV virus or proteins or nucleic acids encoding HIV genes (page 12, lines 3-26). The specification also teaches an exemplary HIV immunogen derived from the HZ321 HIV-1 isolate (page 12, line 27, to page 13, line 3). The specification additionally teaches methods for preparing whole-killed HIV particles and references U.S. Patent No. 5,661,023, which describes methods of making retroviral particles for a variety of human immunodeficiency viruses (page 12, lines 14-26). Applicants submit that the claims recite HIV and that one skilled in the art, based on the teachings in the specification and what was well known in the art, would understand the meaning of an HIV-infected individual and an HIV immunogenic composition. Accordingly, Applicants respectfully submit that the claims are clear and definite and request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 1-26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, is respectfully traversed. Applicants submit that the specification provides sufficient description and guidance to enable the claimed methods.

The specification teaches a variety of suitable HIV immunogenic compositions that include an HIV immunogen, optionally includes an adjuvant, and optionally further includes an immunostimulatory sequence (page 12, line 3, to page 14, line 8). The specification teaches a variety of HIV immunogens that can be used in the claimed methods (page 12, line 14, to page 14, line 8). The specification further teaches compositions and methods for administering an HIV immunogenic composition (page 10, line 21, to page 11, line 11; page 14, line 9, to page 15, line 10). In addition, the specification teaches that 5 of 8 patients

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decreased their viral load from the peak viral load during structured treatment interruption (STI) with the HIV immunogenic composition REMUNE™ (Example I, pages 21-24). Applicants respectfully submit that the specification provides sufficient description and guidance to enable the claimed methods. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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